

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)  
(PCT Article 36 and Rule 70)

REC'D 20 DEC 2005

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Applicant's or agent's file reference 12484540	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. <b>PCT/AU2004/001078</b>	International filing date ( <i>day/month/year</i> ) 12 August 2004	Priority date ( <i>day/month/year</i> ) 12 August 2003	
International Patent Classification (IPC) or national classification and IPC Int. Cl. <sup>7</sup> C07K 14/47, C12N 15/12, A61K 38/17, A61P 3/00, A61P 35/00			
Applicant AGT BIOSCIENCES LIMITED et al			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of 132 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																	
<p>4. This report contains indications relating to the following items:</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application
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Date of submission of the demand 17 November 2004	Date of completion of the report 2 December 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  O.L. CHAI Telephone No. (02) 6283 2482

**Box No. I**      **Basis of the report**

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1 (b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-142 as originally filed/furnished
- pages\* received by this Authority on with the letter of
- pages\* received by this Authority on with the letter of
- ☒ the claims:
- pages as originally filed/furnished
- pages\* as amended (together with any statement) under Article 19
- pages\*143-274 received by this Authority on 17 November 2004 with the letter of 17 November 2004
- pages\* received by this Authority on with the letter of
- ☐ the drawings:
- pages as originally filed/furnished
- pages\* received by this Authority on with the letter of
- pages\* received by this Authority on with the letter of
- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001078

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	YES
	Claims 1-33	NO
Inventive step (IS)	Claims	YES
	Claims 1-33	NO
Industrial applicability (IA)	Claims 1-33	YES
	Claims	NO

## 2. Citations and explanations (Rule 70.7)

The following document was cited in the international search report:

D1 WO 2002/062994

D1 discloses sequence ID Nos 1-5 (AGT 106, 113, 201, 202 and 203) and their use as modulators of physiological processes associated with obesity, anorexia, weight maintenance, impaired muscle development, diabetes and/or metabolic energy levels. Therefore the subject matter of these claims is not new and not inventive, and does not meet the requirements of Article 33(2)-(3) PCT with regards to novelty and inventive step.

Claims 1-33 have industrial applicability.

**Box No. VIII** Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claims 14-16 and 21-27 are not fully supported by the description. These claims are to a method of using a modulator or a composition of modulators. Such modulators or agents encompass an undefined range of compounds that have not been disclosed in the specification. These claims go beyond what has been described in the description.
2. Claim 17 is not clear. The text at the last line repeats the AGTs listed.
3. Claims 1-33 are not supported by the description. In claim 1, the terms 'mitochondrial dysfunction, myopathy, genetic disorder' are broad and include a lot of diseases that the specification does not have any support for. Claims 18, 19, 20 and 31-33 list all imaginable diseases that the specification has not shown any support for.
4. Claims 21-23 are not fully supported by the description. The terms 'derivative, homolog or analog or chemical equivalent or mimetic' are broad and there is no support in the description for such broad claims.
5. Claim 28 is not fully supported by the description. The term 'agent' encompasses an undefined range of compounds that the description has no support for.
6. Claims 29-32 are not fully supported by the description. The method claims merely define a step without defining how the step can be carried out.

## Supplemental Box Relating to Sequence Listing

## Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
  - a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☒ in written format
    - ☒ in computer readable form
  - c. time of filing/furnishing
    - ☒ contained in the international application as filed
    - ☒ filed together with the international application in computer readable form
    - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
    - ☐ received by this Authority as an amendment\* on
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

\* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."